

State of Analysis**PRODUCT:** [REDACTED] Level 3 Modified Rabbit Plasma I.N.R. 2.3-2.5**CODE NO:** 31173**LOT NO:** 07245**DATE OF****ORIGIN:** U.S.A.**MANUFACTURE:** March 13, 2023**STORAGE:** -10 °C to -20 °C for 15 days from DOM; -70 °C or below for 12 months from DOM.**HEALTHY****ANIMAL STATEMENT:** This product is made from raw materials that were collected from animals and found free from obvious signs of infectious and contagious disease.**EU REQUIREMENTS:** Product meets EU requirements for production of technical blood products.**EC 1069/2011:** AR-TEC-0007**PROCEDURE:** Modified rabbit plasma is produced from custom rabbit plasma (Pel-Freez Part # 91162) and adsorbed rabbit plasma (Pel-Freez Part # 81162), using Pel-Freez SMP 31173.

Rabbit blood was collected and processed from New Zealand white rabbits (mixed gender, 8-12 weeks, US grown) at USDA plant P-202 and were found to be free of obvious signs of contagious diseases.

APPEARANCE: Clear, amber fluid**ASSAYS:**

Required Assays	Specification	Result
INR	2.3-2.5	2.3

Meter	Final Bulk	QC Testing (sample 1)	QC Testing (sample 2)	Average QC Testing
UP1296231	2.4	2.3	2.2	2.3
UP1328964	2.4	2.3	2.3	2.3
UP1118104	2.4	2.2	2.3	2.3
UP1374533	2.4	2.2	2.3	2.3
UP01452205	2.3	2.3	2.3	2.3

INR obtained using [REDACTED] meter. Key code: S-113 XSPT

Test strips: code S- [REDACTED] 10

QUALITY ASSURANCE

Quality Control Release Date:

March 16, 2023



Doug Stocker

Bio Quality Systems Technician I

Results pending ☐Meets or exceeds specifications ☒Does not meet specifications ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**